

PATENT
2801-0165P

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: Russell M. Hagen et al. Conf.: 4024
Appl. No.: 09/985,679 Group: 1617
Filed: November 5, 2001 Examiner: R. TRAVERS
For: NOVEL MEDICAL USE FOR TACHYKININ
ANTAGONISTS

INFORMATION DISCLOSURE STATEMENT
(SUBMISSION AFTER FILING OF AN APPLICATION
BUT BEFORE FINAL REJECTION OR NOTICE OF ALLOWANCE
OR CONCURRENTLY WITH A RULE 1.114 RCE APPLICATION)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

February 17, 2004

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-1449(s), attached hereto.

II. COPIES (check at least one box)

- a. ☒ This application was filed before June 30, 2003. Accordingly, submitted herewith is a legible copy of (i) each U.S. and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
- b. ☐ This application was filed on or after June 30, 2003. Accordingly, copies of cited U.S. patents and patent application publications therefore are not included. Copies of foreign patent documents and non-patent literature are included.

- c. ☒ Some or all of the documents listed on the PTO-1449 are not enclosed because they were filed with the Reply under 37 C.F.R. 1.111 filed January 23, 2003 and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

III. CONCISE EXPLANATION OF THE RELEVANCE
(check at least one box)

- a. ☒ **DOCUMENTS IN THE ENGLISH LANGUAGE**

The patents, publications, or other information listed on the attached PTO 1449 are in the English language and therefore, do not require a statement of relevancy.

- b. ☒ **DOCUMENTS NOT IN THE ENGLISH LANGUAGE**

A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

An English language abstract of JP 62-252764 is attached thereto.

An English language abstract of JP 60-214784 is attached thereto.

- c. ☐ **ENGLISH LANGUAGE SEARCH REPORT**

An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).

- d. ☒ **OTHER**

The following additional information is provided for the Examiner's consideration.

JP 3-503768 corresponds to WO 90/05729.

An English translation of the Japanese reference New Compendium of Internal Medicine, 1, pp. 281-294 (1975) is not readily available. Applicants are attempting to obtain a translation.

An English translation of the Japanese reference New Compendium of Internal Medicine, 6, pp. 173-188 (1977) is not readily available. Applicants are attempting to obtain a translation.

An English translation of the Japanese reference "Brain & Nerve", 20, pp. 959-963 (1968) is not readily available. Applicants are attempting to obtain a translation.

FEES

IV. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b):
(check one box)

- a. ☐ within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required. (*This section is not to be used with RCE's.*)
- b. ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.
- c. ☐ concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.
- d. ☐ before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required.
In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

- V. ☒ THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):
(check one box)

before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

- a. ☒ No statement; therefore, a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).
or
b. ☐ See the statement below. No fee is required.

- VI. STATEMENT UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby states that

- a. ☐ each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.
- c. ☐ Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VII. PAYMENT OF FEES (check one box)

- ☒ A check in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p) is enclosed for the above-identified fee.
- ☐ Please charge Deposit Account No. 02-2448 in the amount required by 37 C.F.R. § 1.17(p) for the above-indicated fee. A triplicate copy of this paper is attached.
- ☐ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.


If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 
Gerald M. Murphy, Jr., #28,977

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Falls Church, VA 22040-0747
(703) 205-8000


GMM/KJR/jao
2801-0165P

Attachment(s) : ☒ PTO-1449
☒ Documents
☐ Foreign Search Report
☒ Fee
☐ Other:

Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)	ATTY. DOCKET NO. 2801-0165P	APPLICATION NO. 09/985,679
	APPLICANT Russell M. Hagen et al.	
	FILING DATE November 5, 2001	GROUP 1617

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	Kind	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	US 4,920,227		04-24-1990	Pelletier et al.			
	US 5,576,317		11-19-1996	Gonsalves			
	US 4,695,578		09-22-1987	Coates et al.			
	US 4,886,808		12-12-1989	King			

FOREIGN PATENT DOCUMENTS

	Office	DOCUMENT NUMBER	Kind	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
								YES	NO
		JP 3-503768		08-22-1991	Japan				
		WO 90/05729		05-31-1990	PCT				
		0 394 989		10-31-1990	EPO				
		JP 62-252764		11-04-1987	Japan			Abst	

OTHER DOCUMENTS

(Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.

	Proceedings of "Substance P and Neurokinins - Montreal 1986", A Satellite Symposium of the XXX International Congress of the International Union of Physiological Sciences, J.L. Henry et al., Editors
	Peter Ward et al., J. Med. Chem., 38, pp. 4985-4992 (1995)
	David O. Carpenter et al., Cellular and Molecular Neurobiology, 3(2) pp. 113-126 (1983)
	A.F. Ghouri et al., Anesthesiology, 73(3A) p. 9 (September 1990)
	Domenico Regoli et al., TIPS, 9, pp. 290-295 (August 1988)
	P.L.R. Andrews et al., TIPS, 9, pp. 334-341, (September 1988)
	Brown et al., Tachykinin Antagonists, Hakanson R. and Sundler, F. (Eds.) Elsevier:Amsterdam, pp. 305-312 (1985)
	J.W. Dalley et al., Journal of Psychopharmacology, 4(4), p. 285, 1990 (Abstract)
	David O. Carpenter et al., Final Report No. USAFSAM-TR-83-41, Peptide-Induced Emesis in Dogs, October 1983
	T.D. Walsh et al., The Pharmaceutical Journal, pp. 525-527 (October 29, 1983)

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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	US 5,202,333		04-13-1993	Berger et al.			
	US 4,906,755		03-06-1990	Gittos			

FOREIGN PATENT DOCUMENTS

	Office	DOCUMENT NUMBER	Kind	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
								YES	NO
		JP 60-214784		10-28-1985	Japan				
		0 436 334 A2		07-10-1991	EPO				

OTHER DOCUMENTS

(Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.

	Vincent Gotz et al., ON CONTINUING PRACTICE, 8(4), pp. 11-20 (1981)
	Shinya Ueno et al., Life Sciences, 41(4), pp. 513-518 (1987)
	Shinya Ueno et al., Life Sciences, 43(5), pp. 413-420 (1988)
	G. A. Saab, Am J Clin Oncol, 11(4), pp. 470-473 (1988)
	Kathryn Louise Wood, Ph.D Thesis, Univ. London, 1988, paragraphs 2.5 and 2.7
	R.A. Leslie, Neurochem. Int., 7(2), pp. 191-211 (1985)
	David O. Carpenter et al., Final Report No. USAFSAM-TR-82-28, USAF School of Aerospace Medicine, 1982, paragraph 2.8
	J.P. Miolan et al., Neuropeptides, 12, pp. 243-248 (1988)
	V.V. Yasnetsov et al., Byulleten Eksperimentalnoi Biologii I Meditsiny, 103(5), pp. 586-588 (May 1987) (Translation)
	V.S. Shashkov et al., Farmakologiya I Toksikologiya, 51(2), pp. 30-36, (March-April 1988) (Translation)
	Yu. V. Drozd et al., Byulleten Eksperimentalnoi Biologii I Meditsiny, 106(7), pp. 50-52 (1988) (Translation)
	V.V. Yasnetsov et al., Kosmicheskaya Biologii I Aviakosmicheskaya Meditsina, 22(2) pp. 72-73 (1988) (Translation)

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	US 5,360,800		11-01-1994	Coates et al.					
	US								
FOREIGN PATENT DOCUMENTS									
	Office	DOCUMENT NUMBER	Kind	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
		0 247 266		12-02-1987	EPO			YES	NO
		GB 2 152 049A		07-31-1985	Great Britain				
		GB 2 100 259A		12-22-1982	Great Britain				
OTHER DOCUMENTS (Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.)									
	R. Michael Snider et al., Science, Reports, pp. 435-437, (Jan. 25, 1991)								
	Patrick W. Mantyh, J. Clin. Psychiatry, 63, Suppl. 11, pp. 6-10, (2002)								
	Dan L. Longo et al., Cancer Treatment Reports, 66(11), pp. 1975-1976 (November 1982)								
	Nicolas Tsavaris et al., Journal of Pain and Symptom Management, 6(8), pp. 461-465, November 1991								
	Merck Index, 11 th Ed, p. 1082 (1989)								
	New Compendium of Internal Medicine, 1, pp. 281-294 (1975)								
	New Compendium of Internal Medicine, 6, pp.173-188 (1977)								
	Brain & Nerve, 20, pp. 959-963 (1968) (with English abstract)								
	Dam et al., Peptides, (7), pp. 855-864 (1986)								
	Butler, A., et al., Pharmacological Properties of GR 38032F, a novel antagonist at 5-HT ₃ receptors, BRITISH JOURNAL OF PHARMACOLOGY, 94(2), pp. 397-412 (1988)								
	Bradley et al., "Proposal for the Classification and Nomenclature of Functional Receptors for 5-hydroxytryptamine," Neuropharmacology, 25(6), pp. 563-576 (1986)								
EXAMINER					DATE CONSIDERED				
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Sheet 4 of 4 (02-17-2004)

Form PTO-1449

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	US						
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	US						
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	Office	DOCUMENT NUMBER	Kind	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
								YES	NO

OTHER DOCUMENTS (Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.)

	Dutta, A.S., "Tachykinin Receptors". Comprehensive Medicinal Chemistry, 3, pp. 1001-1022, Ed. Emmett, J.C. (1990)
	J. Fozard et al., Blockade of Neuronal Tryptamine Receptors by Metoclopramide, European Journal of Pharmacology, 49, pp. 109-112 (1978)
	J. Fozard et al., Blockade of Serotonin Receptors on Autonomic Neurones by (-) Cocaine and Some Related Compounds, European Journal of Pharmacology, 59, pp. 195-210 (1979)
	Physician's Desk Reference Listing
	Electronic Orange Book Listings for Ondansetron, Granisetron, Palonosetron, Dolasetron and Alosetron

EXAMINER

DATE CONSIDERED

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